

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

NATIONAL INFUSION CENTER
ASSOCIATION, on behalf of itself and its
members; GLOBAL COLON CANCER
ASSOCIATION, on behalf of itself and its
members; and PHARMACEUTICAL
RESEARCH AND MANUFACTURERS OF
AMERICA, on behalf of itself and its
members,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the U.S. Department of Health
and Human Services; the U.S. DEPARTMENT
OF HEALTH AND HUMAN SERVICES;
CHIQUITA BROOKS-LASURE, in her
official capacity as Administrator of the
Centers for Medicare and Medicaid Services;
and the CENTERS FOR MEDICARE AND
MEDICAID SERVICES,

Defendants.

Civil Action No. 1:23-cv-00707

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE*

Pursuant to Federal Rule of Civil Procedure 7 and Local Rule CV-7(b), the Biosimilars Forum (the “Forum”) respectfully moves this Court for leave to file the attached brief as *amicus curiae* in support of plaintiffs’ motion for summary judgment. The Forum has consulted with counsel for the parties regarding this motion, and all parties have consented to the relief requested herein.

Although the Federal Rules do not specifically address the filing of *amicus* briefs in district court, it is well-established that this Court has “inherent authority” to allow the participation of *amici curiae*. See *Pachecho v. Freedom Buick GMC Truck, Inc.*, No. 10-cv-116, 2011 WL

13234884, at *1 (W.D. Tex. Nov. 1, 2011). The Forum submits that the proposed *amicus* brief will be helpful to the Court as it considers the important constitutional issues raised in plaintiffs’ motion.

The Forum is an independent nonprofit trade association dedicated to advancing biosimilar medicines in the United States. Biosimilars are analogous to generic drugs in that they rely on FDA’s safety and efficacy determinations for previously approved biological products. The Forum’s proposed *amicus* brief explains the adverse consequences of the Inflation Reduction Act (“IRA”) on the biosimilars industry—and the millions of patients who stand to benefit from improved access to critical medicines thanks to biosimilars—reflecting the harms that flow from the IRA’s unconstitutional delegation of unchecked regulatory power and its denial of basic protections required by due process. The Forum’s brief also provides specific examples that illustrate how the IRA’s attempt to insulate implementation of the Act from public input and judicial review has already led the responsible agency to take aggressive positions that contravene the statutory scheme and exacerbate the harm to biosimilar competition.

For these reasons, the Forum respectfully requests that the Court grant this motion and permit the Forum to file its proposed *amicus* brief, which is attached hereto as **Exhibit A**.

Respectfully submitted,

/s/ J. Carl Cecere

J. Carl Cecere
State Bar No. 24050397
ccocere@cecerepc.com
Cecere PC
6035 McCommas Blvd.
Dallas, TX 75206
(469) 600-9455

Dated: August 24, 2023

Counsel for The Biosimilars Forum

CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

/s/ J. Carl Cecere

J. Carl Cecere